REMARKS

Applicant respectfully requests entry of the amendment and reconsideration of the claims. Applicants respectfully request reconsideration and withdrawal of the pending rejections under 35 U.S.C. § 112, first paragraph.

Claim Amendments

Applicant has amended claims 2, 5, 9, 14, and 17-19 to add a Markush group reciting specific acetylcholine esterase antagonist. Support can be found throughout the specification, including at page 10, lines 6-14.

Applicant has amended claims 22-28 to correct the obvious typographical error of omitting the term "antagonist". Support can be found throughout the specification, including at page 4, lines 12-14.

Applicant has also amended to claim 28 to correct an obvious typographical error.

New claims 43-45 have been added. Support can be found throughout the specification, including at page 10, lines 6-14 and at page 17, lines 19-27.

No new matter has been added through the amendments or the new claims.

Written Description

The Examiner rejects claims 2-3, 5-6, 8-15, 17-33, 35-36, and 41 under 35 U.S.C. § 112, first paragraph, for allegedly failing to satisfy the written description requirement. Under 35 U.S.C. §112, first paragraph, a patent specification must contain sufficient written description in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention (*Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)). "The specification must teach the invention by describing it." (*Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 926 (Fed. Cir. 2004)). Applicant has amended claims 2, 5, 9,

14, and 17-19 to add a Markush group reciting "an acetylcholine esterase antagonist selected from the group consisting of donepezil, galanthamine, rivastigme, tacrine, physostigmine, neostigmine, edrophonium, demecarium, pyridostigmine, phospholine, metrifonate, zanapezil, and ambenonium." The specific acetylcholine esterase antagonists recited in the Markush group are described in the specification at page 10, lines 6-14. Applicants respectfully submit that these amendments render this rejection moot. Applicant respectfully requests removal of this rejection.

Further Arguments

The Examiner rejects all pending claims as failing to comply with the written description requirement under 35 USC 112, first paragraph. Specifically, the Examiner contends that the claims contain subject matter which is not described in the specification in such a way is to reasonably convey to one skilled in the relevant art that the inventor had possession of the claimed invention at the time the patent was filed.

This rejection is similar to a rejection raised in a previous office action, and previously traversed by the Applicant. The Examiner contends that the previous traversal was not persuasive because the current amended claims read on any acetylcholine esterase antagonists. The Examiner contends that "clearly" not every acetylcholine esterase will reduce insulin resistance in a mammalian patient. Applicant believes the Examiner accidentally omitted the word "antagonist" from this statement.

The Examiner does not provide any justification or reason behind this purportedly clear statement (i.e. that not every acetylcholine esterase antagonist will reduce insulin resistance in a mammalian patient). In fact, the Applicant's disclosure, and the mechanism of action discussed and disclosed within the patent application, teaches that every acetylcholine esterase antagonist will reduce insulin resistance in a mammalian patient.

The Examiner contends that there are over 151,424 acetylcholine esterase antagonists.

Applicant kindly requests support for this statement.

Further the Examiner states that there are apparently contradicting statements in claims one and five, wherein claim one requires an acetylcholine esterase (sic) for reducing insulin resistance and claimed five requires an acetylcholine esterase (sic) for increasing skeletal muscle glucose uptake. The Examiner questions how the acetylcholine esterase (antagonist) will both reduce at one site and increase at another. Applicant submits that this contention scientifically flawed, and submits that these two actions of the acetylcholine esterase inhibitor clearly are not contradictory.

The Examiner further states that a lack of adequate written description also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. Specifically, a laundry list disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species. The Examiner contends that there is a lack of adequate written description because the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. Specifically, the Examiner contends that the written description requirements may be satisfied through sufficient description of the representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics. Examiner contends that the disclosure of only one species encompassed within a genus adequately describes a claim directed to a genus only if the disclosure indicates that the patentee has invented species sufficient to constitute the genus. The Examiner contends that Applicant has not provided a description of the structure of the representative number of compounds, a description of the chemical and/or physical characteristics of representative number of compounds, or a description of how to obtain the representative number of specific compounds. Thus, the Examiner contends that the Applicant has not described with sufficient clarity with these acetylcholine esterase antagonists are.

Again, Applicant respectfully traverses. Applicant respectfully submits that the Examiner's contentions that there are known acetylcholine esterase antagonists, and that Applicant has not described with sufficient clarity what an acetylcholine esterase antagonist is are contradictory statements. Applicant submits that several acetylcholine esterase antagonists are known in the art. The field of acetylcholine esterase, and antagonists to same, is a very well-developed field of art, and any person within the field would be capable of determining whether any one particular compound is an acetylcholine esterase antagonist or not. Such determination can be made using routine experimentation, for example enzyme activity assays, and are routinely and commonly used by those with knowledge in this field. As such, Applicant has fully and completely described, using the chemical characteristics of a representative number of compounds, what is claimed.

Solely in an effort to expedite prosecution, and in a non-prejudicial manner that should by no means be considered an agreement with the Examiner's characterization of the validity of the claims, Applicant has amended all dependent claims to a specific subset of acetylcholine esterase antagonists. The claimed acetylcholine esterase antagonists are both clearly defined, and enabled by the specification. The claimed acetylcholine esterase antagonists are all well known in the art, and are all a part of a known and recognized class of drugs called "acetylcholine esterase antagonists". Applicant submits that a person skilled in the art would readily understand that the experiments and examples provided in the specification related to neostigmine would equally apply to any of the claimed acetylcholine esterase antagonists. In support of this, Applicant provides a paper which summarizes the current state of the art in relation to acetylcholine esterase antagonists, Jann et al (Clinical Pharmacokinetics and Pharmacodynamics of Cholinesterase Inhibitors, Clin Pharmacokinet 2002:41 (10):719-739).

This review paper demonstrates that acetyl cholinesterase inhibitors are a well-defined and understood class of compounds. Acetyl cholinesterase inhibitors are a known class of drugs that are routinely interchanged in pharmacology, and interchanging these drugs is a matter of

routine experimentation and in the "normal course" for treatment with acetyl cholinesterase antagonists. See Jann et al, for example, at the Abstract, where minor, subtle differences between the acetyl cholinesterase inhibitors are discussed. Also see the same paper, on page 721, under the heading "Pharmacokinetic Aspects", where it is acknowledged that the pharmacokinetics and pharmacodynamics of the compounds vary, which results in different dosing regimens *or the rationale for switching drugs during treatment*, showing again that acetyl cholinesterase antagonists are largely and routinely interchangeable in treatment, and optimized through a treatment regimen. Determining the appropriate dosage or type of acetyl cholinesterase inhibitor is largely a matter of routine experimentation, with a method of such experimentation described in Jann et al., at page 732, heading 4.1.2.

Thus limiting the invention to one specific acetyl cholinesterase antagonist unnecessarily and inappropriately limits the invention beyond what has been invented, namely, the use of an established class of drug in a novel manner.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the objections under 35 USC 112, first paragraph (written description).

35 USC 112, first paragraph (enablement)

The Examiner rejects claims 2-3, 5-6, 8-15, 17-33, 36, and 41 under 35 U.S.C. § 112, first paragraph, for an alleged lack of enablement. The Examiner asserts that the specification is enabling for altopine [sic] and neostigmine, but the specification does not reasonably provide enablement for the wide variation of acetylcholine esterase antagonists, and the wide variation of other drugs. Applicant respectfully traverses.

To meet the enablement requirement of 35 U.S.C. §112, first paragraph, a specification must contain a sufficient description to enable one skilled in the art to make and use the claimed invention (*See, e.g., Chiron Corp. v. Genentech, Inc.,* 363 F.3d 1247, 1253 (Fed. Cir. 2004); MPEP §2164.01). A specification does not need to explicitly disclose every detail, and may omit

what is well known in the art (*In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991); MPEP 2164.01). To make and use an invention may require experimentation even if the specification is enabling (*In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984); MPEP §2164.01). The experimentation must not be unduly extensive (*Id.*), however, costly and timely experimentation alone does not constitute undue experimentation. (*U.S. v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988)).

Solely to expedite prosecution, Applicant has amended the claims to recite an acetylcholine esterase antagonists selected from a Markush group of 13 such compounds. Among the 13 compounds recited in the Markush group is neostigmine, which the Examiner has stated is enabled by the instant specification. Applicant asserts that it is the mechanism of action that is required for the acetylcholine esterase antagonist and not its exact structure. For at least these reasons, Applicant respectfully asserts that the Markush group of compounds is fully enabled by the specification.

Applicant also respectfully submits that the Examiner has not established that undue experimentation is necessary to practice the claimed subject matter. Applicant respectfully asserts that it would not be undue experimentation to test the 12 remaining known acetylcholine esterase antagonists. "[T]he mere fact that the experimentation may have been difficult and time consuming does not mandate a conclusion that such experimentation would have been considered to be 'undue' in this art." *Falkner v. Inglis*, 448 F.3d 1357, 1365 (Fed. Cir. 2006). Applicant respectfully asserts that the Examiner has not established that undue experimentation is necessary. For at least this reason, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph for an alleged lack of enablement.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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